REMARKS

Applicants respectfully request that the Information Disclosure Statement filed on Novemeber 29, 2007 be considered. Acknowledgement to that effect is requested in the next Office Action.

The present application contains claims 1-173, the status of which is as follows:

(a) Claims 1-50, 52-69, 71-95, and 97-173 have been canceled without prejudice.

(b) Claims 51, 70 and 96 are currently amended.

Applicants thank Examiners Maewall and Gollamudi for the courtesy of an interview with the Applicants' representative, Sanford T. Colb (Reg. No. 26,856) on September 10, 2008. Mr. Colb submitted that the Examiner had rejected at least claim 51 without having provided grounds for the rejection of the claim. Mr. Colb proposed amending claim 51 to incorporate therein the limitations of the claims from which claim 51 depended. No agreement was reached with the Examiners.

Applicants note that, in the Applicants' response to the previous Office Action, claims 131-173 were mistakenly marked "withdrawn." The aforementioned claims should have been marked "canceled," and are correctly marked in the present response.

Independent claim 51 has been amended to incorporate therein the limitations of claims 1 and 48, as previously pending. Claim 51 as previously pending was dependent on claims 1 and 48. Therefore, claim 51 as currently amended is identical in scope to claim 51 as previously pending. Claim 51 recites a capsule, which comprises (in addition to the components recited in previously pending claim 1) a needle, and an elastic element. The elastic element (a) maintains the sharp tip of the needle at an original position that is substantially within the capsule, prior to a change of state of the pH-sensitive coating, (b) changes shape in a manner that permits the sharp tip of the needle to contact the layer of the gastrointestinal tract, in response to the action of the control component, and (c) causes the sharp tip of the needle to withdraw to the original position at a time after initiation of the passage of the drug through the layer.

This embodiment is illustrated in Figs. 29A and 29B of the application, which show a needle 220, and elastic elements 222, as recited in the above claim.

FIG. 29A

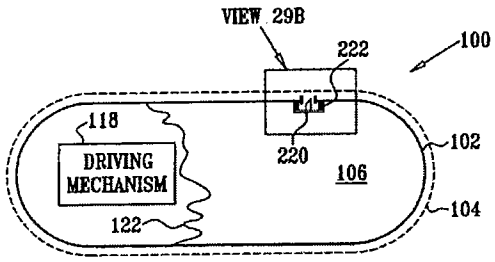
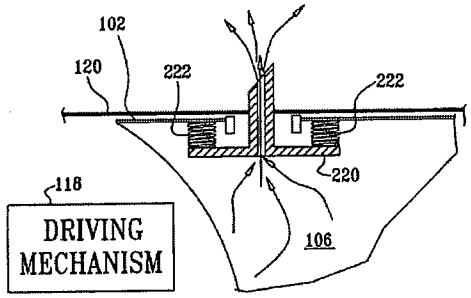


FIG. 29B



The Examiner rejected claim 51 under 35 U.S.C. 103(a) over GB 2,374,149 to Thomas, in view of the combination of references of US Patent 6,453,199 to Kobozev, US Patent 5,925,030 to Gross, and PCT Publication WO 02/098501 to Keisari. Applicants submit that the Examiner did not clearly explain the pertinence of the cited prior art to claim 51. The only reference made to a needle (or something similar to a needle) in the cited prior art is an injector mechanism, which is described in the Keisari PCT application. Keisari describes an apparatus for treating tumor cells by driving an electric current into the cells. Keisari further describes an injector system that forms part of an **external-to-the-body** electrode system, the injector system being for injecting an agent into tumor cells, and the electrode system for driving a current into the tumor cells. **Keisari does not describe a needle for incorporation into a capsule**, the capsule also comprising an elastic element for controlling the action of the needle, while the capsule is in a subject's gastrointestinal tract, in the manner described above. The apparatus of claim 51 is not obvious in light of Keisari, who described an injector system that forms part of an electrode system, **since Keisari does not describe an injector system for use inside the subject's gastrointestinal tract** in the manner recited in claim 51. **Keisari's injector system is not described as being used on internal tissue, and the electrodes of the Keisari system are described as being positioned by a user**.

Applicants emphasize that Keisari does not describe or suggest <u>any</u> of the following limitations that were recited in claim 51 (or claims from which it depended), prior to the previous office action:

> wherein the tip of the needle is adapted to <u>contact the layer of the gastrointestinal tract in response to the change of state of the pH-sensitive coating</u>,

> wherein the capsule comprises an elastic element, adapted to maintain the sharp tip of the needle at an original position that is substantially within the capsule, prior to the change of state,
>
> wherein, in response to an action of the control component, the elastic element is adapted to change shape in a manner that permits the sharp tip of the needle to contact the layer of the gastrointestinal tract, and
>
> wherein, at a time after initiation of the passage of the drug through the layer, the elastic element is adapted to cause the sharp tip of the needle to withdraw to the original position.

In light of the complete absence from Keisari of these four substantive features in claim 51, Applicants respectfully submit that that the rejection of this claim was improper. Additionally, since claim 51 as currently amended is substantively identical to claim 51 as previously pending, the current amendment of claim 51 does not introduce new matter. Applicants believe this claim to be patentable over all art known to the Applicants, and respectfully request that if the Examiner disagrees, then clear arguments to the contrary should be included in the next office action.

Independent claim 70 has been amended to incorporate therein the features of claims 1, 59, and 67 as previously pending. Claim 70 as previously pending was dependent from claims 1, 59, and 67. Therefore, claim 70 as currently amended is identical in scope to claim 70 as previously pending. Claim 70 recites a capsule that drives two currents into the gastrointestinal tract, a first current for opening the tight junctions, and a second current for iontophoretically driving the drug into the gastrointestinal tract. The Examiner rejected claim 70 under 35 U.S.C. 103(a) over the combination of prior art references cited hereinabove. However, **no indication was provided as to which of the cited prior art references render obvious** a capsule, as described in claim 70, that drives **two types of current, via respective sets of electrodes, the currents having respective effects on the subject's gastrointestinal tract, and the sets of electrodes being disposed on a single ingestible capsule**.

In light of the complete absence from the cited art of this important, substantive limitation in claim 70, the Applicants respectfully submit that that the rejection of this claim was improper. Additionally, since claim 70 as currently amended is substantively identical to claim 70 as previously pending, the current amendment of claim 70 does not introduce new matter. Applicants believe this claim to be patentable over all art known to the Applicants, and respectfully request that if the Examiner disagrees, then clear arguments to the contrary should be included in the next office action.

Independent claim 96 has been amended to incorporate therein the features of claims 1 and 94 as previously pending. Claim 96 as previously pending was dependent from claims 1 and 94, therefore claim 96 as currently amended is identical in scope to claim 96 as previously pending. Claim 96 recites a capsule that includes (in addition to the components recited in previously pending claim 1) a piston, and a piston driver, the piston driver comprising a spring-like mechanical element that drives the piston to drive the drug from the capsule. This embodiment is shown in Figs. 27A-B. Piston 202 is held in place by portion 204, which is a pH-sensitive adhesive. In the gastrointestinal tract, portion 204 dissolves, freeing piston 202. Piston-driver 200, which is a spring, expands, advancing the piston head, which forces drug 106 out of orifice 110.

FIG. 27A

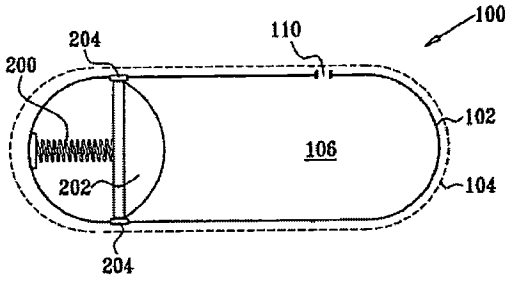
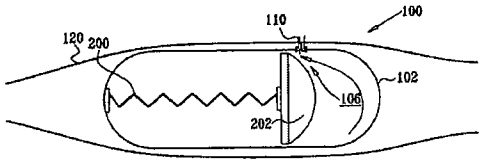


FIG. 27B



The Examiner rejected claim 96 under 35 U.S.C. 103(a) over the combination of prior art references cited hereinabove. Applicants submit that the Examiner did not clearly state the pertinence of the prior art references to claim 96. None of the prior art references cited by the Examiner in the Office Action describe a piston disposed inside a capsule, for driving a drug from the capsule, as described in claim 96. Although other driving mechanisms are described in some of the cited references, **using a piston as the driving mechanism would not be obvious, since the use of a piston inside a capsule requires a mechanism for holding the piston head in place prior to activation,** which (as described in the present application) is provided by the pH-sensitive adhesive, as described above.

Summary of Applicants' request for Examiner's reconsideration of the pending rejected claims, without requiring an RCE

37 CFR 1.104(c)(2) states:

> *(2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.*

Applicants respectfully submit that the Examiner did not designate the particular parts of the cited prior art that were relied upon in the Examiner's rejection of claims 51, 70 and 96. Furthermore, the Examiner did not clearly explain the pertinence of each of the prior art references to the aforementioned claims. Therefore, Applicants submit that the aforementioned claims were not rejected in accordance with 37 CFR 1.104(c)(2) and that those claims should not have the status of being finally rejected.

Claims 1-7, 10-22, 26-27, 36, 41-44, 48-50, 52-57, 59, 61-69, 79-87, 89-95, and 97-130 were rejected in view of the prior art references cited hereinabove. Claims 58 and 88 were also rejected in view of the prior art references cited hereinabove, further in view of "Iontophoresis-enhanced absorptive flux of polar molecules across intestinal tissue in vitro," by Leonard. While not necessarily agreeing with these rejections, Applicants have canceled the above claims without prejudice.

Applicants believe the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection and objection raised by the Examiner. In view of these amendments and remarks, Applicants respectfully submit that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

RatnerPrestia

Jacques L. Etkowicz, Reg. No. 41,738
Attorney for Applicants

JLE/kpc

Dated: November 7, 2008

P.O. Box 980
Valley Forge, PA 19482
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being electronically transmitted to: Commissioner for Patents, Alexandria, VA on November 7, 2008.

Kathleen P. Carney